IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Calhoun et al.	/	
U.S. Serial No: 10/632,014	/	Group Art Unit: 1616
Filed: July 31, 2003	/	Examiner: SOROUSH, ALI
For: APPARATUS AND METHOD FOR PREVENTING ADHESIONS BETWEEN AN IMPLANT AND SURROUNDING TISSUES	/	

Mail Stop Board of Patent Appeals and Interferences
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR "PRE-APPEAL BRIEF" REVIEW

Dear Madam/Sir:

Applicants submit this Request with the filing of a Notice of Appeal from the decision of the Examiner of Group Art Unit 1616 in the Final Office Action dated January 6, 2010, rejecting all pending claims 1-29 and 34-36, and the later-issued Advisory Action.

A Listing of Claims is provided in Appendix A of this paper. Of the claims set forth in that appendix, claims 1, 2, 4-29 and 34-36 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Bakker et al. (US Patent 5,508,036), and claim 3 is rejected as allegedly being unpatentable over Bakker et al. in view of Massie et al. (Anti-Fibrotics in the prevention of epidural fibrosis: Gels versus a barrier sheet) as, according to the Final Office Action, "evidenced by Welch et al. (Use of polylactide resorbable fim as an adhesion barrier…)." Applicants respectfully submit that claims 1-29 and 34-36 are patentable over the prior-art of record at least on the grounds as follows.

I. Office Action Impropriety -- No Treatment of Claim Limitations

The Final Office Action is improper, since, for example, the Final Office Action did not treat, or even address, the substantive, positively-claimed limitations of many and indeed most of the claims. As a consequence of not addressing important limitations, the Final Office Action is inappropriate, improper, and fatally erred.

Each of the pending claims is a method claim. The Final Office Action did not appear to recognize the existence of the below process limitations, which are: (1) clearly recited in the pre-existing claims; (2) not in the cited prior art; (3) argued in Applicants' prior Amendment; and (4) not addressed in the Final Office Action's response to Applicants' arguments:

a. "applying…material…to thereby cover *substantially all* exposed surfaces of the implant" (claim 1);

b. "applying…material…around the implant…wherein…comprises…an edge *which is thicker*" (claim 1);

c. "*applying* the *implant and…membrane* to…a region…susceptible to adhesions" (claim 1);

d. "*applying…and attenuating…adhesions…at the region* within the human patient" (claim 1);

e. "applying…and attenuating…wherein...membrane…comprises a *single layer*" (claim 2);

f. "applying…and attenuating…wherein…the edge is *2 to 4 times thicker*" (claims 2-6, 14, 19, 21, 34, 36);

g. "wherein…the step of applying…comprises *heat-shrinking*…around the implant" (claim 6); and

h. "wherein the step of applying…comprises: *dissolving a polymer*…and coating" (claims 7-13).

Each of the above items must be addressed by the Examiner. Applicants previously made the above distinctions, but the Final Office Action did not even acknowledge them.

According to the Manual of Patent Examining Procedure (MPEP) Section 707.07(g), every issue that stands between the Applicants and allowance of the application needs to be identified by the Examiner, by clearly and crisply presenting the best case against patentability. (See, for example, MPEP Sections 2164.04 and 2106(II) "[i]t is essential…complete

examination…[u]nder the principles of compact prosecution…state all reasons and bases for rejecting claims"). In theory, this provides the Applicants with the opportunity to respond to each issue so that, if each issue is successfully rebutted or otherwise addressed, the application would be in condition for allowance. Conversely, if the Applicants are not successful, the application is in better condition for appeal. A failure to provide the best case such that a new rejection, new art, and/or expanded arguments are required in a subsequent Office Action generally precludes the finality of that subsequent Office Action. (See MPEP Section 706.07(a).) In practice, this prevents piecemeal prosecution of the application, which the MPEP instructs should be avoided. (See MPEP Section 707.07(g).)

II. Office Action Impropriety -- No Provision of Motivation-To-Combine

No motivation to combine was provided on page 7 of the Final Office Action. The only content on the topic states "[i]t would have been obvious…to combine…to use the barrier sheet of Massie et al. in device of Bakker et al. in order to provide an anti-adhesive implant for use in back surgery." This content is devoid of any motivation, whatsoever.

As a general principal, it is the Applicants, rather than the Examiner, who should be regarded as the relevant audience for the undertaking of an analysis on the sufficiency of the clarity of a reasoned rejection being applied against the Applicants. In the present situation, it is believed that not even a skilled patent practitioner can be expected to understand the Examiner's silence on how one skilled in the art would have been motivated to combine the various alleged teachings of the cited references. It is well established in the patent law, as set forth in, for example, In re Oetiker, 24 USPQ2d 1443, 1447 (Fed. Cir. 1992) that "[t]he examiner cannot sit mum, leaving the applicant to shoot arrows in the dark hoping to somehow hit a secret objection harbored by the examiner. The 'prima facie case' notion, . . . , seemingly was intended to leave no doubt among examiners that they must state clearly and specifically any objections (the prima facie case) to patentability, and give the applicant fair opportunity to meet those objections with evidence and argument. To that extent the concept serves to level the playing field and reduces the likelihood of administrative arbitrariness."

The proper question is not whether it would have been obvious to the hypothetical addressee who was presented with an ex post facto selection of prior specifications that elements

from them could be combined to produce a new process. It is rather whether it would have been obvious to a non-inventive skilled worker in the field to select from a possibly very large range of publications the particular combination subsequently chosen by the opponent in the glare of hindsight and also whether it would have been obvious to that worker to select the particular combination of integers from those selected publications. In the case of the current combination of claimed process elements, "invention" lies at least in part in the selection of integers, a process which will necessarily involve rejection of other possible integers. The prior existence of publications revealing those integers, as separate items, which *has not* even been established, and other possible integers would not of itself make the present invention obvious. It is the selection of the integers out of, perhaps many possibilities, which must be shown to have been obvious. Moreover, even if one were to combine the base reference with any one or more of the other relied-upon references as set forth in the outstanding Final Office Action, Applicants submit that none of the presently claimed combinations of limitations would be obtained.

Applicants are hopeful that the Office can appreciate the need, or at least the benefit and apparent suitability, for additional clarity, and, accordingly, Applicants earnestly request specifically elucidation on how one of ordinary skill would have considered it to be obvious to **incorporate** the teachings of the Massie et al. method into the method of Bakker et al.

Furthermore, in support of Applicants' request, the Office's attention is directed to Section 2141 of the MPEP, which advises on what Applicants consider the frequent desirability and appropriateness to "include **explicit** findings as to **how** a person of ordinary skill would have **understood prior art teachings**" (emphasis added).

This same MPEP section continues, stating as follows: "Office personnel must provide an **explanation to support** an obviousness rejection … 35 U.S.C. 132 requires that the applicant be notified of the **reasons** for the rejection of the claim so that he or she can decide how best to proceed. **Clearly** setting forth … the **rationale(s)** to support a rejection in an Office action leads to the prompt resolution of issues pertinent to patentability."

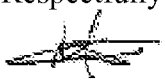
For the foregoing reasons, Applicants respectfully submit that the Final Office Action is improper, and request treatment of each of the above claim limitations, addressing of each of Applicants' arguments relating to the above claim limitations, and further establishing a *prima facie* case of obviousness.

III. Conclusion

In light of the above reasons, Applicants respectfully submit that all of the presently pending claims are patentable. It is respectfully submitted that all pending claims should be allowed. Accordingly, reversal of the Examiner's rejections is respectfully solicited.

The Commissioner is hereby authorized to charge any needed fees to Deposit Account 50-1600.

Respectfully submitted,



Kenton R. Mullins
Attorney for Applicants
Registration No. 36,331

Dated: April 6, 2010

Stout, Uxa, Buyan & Mullins, LLP
4 Venture, Suite 300
Irvine, CA 92618
Telephone: (949) 450-1750
Facsimile: (949) 450-1764

APPENDIX A

This Listing of Claims will replace all prior versions, and listings, of claims in the application:

1. (Previously Presented) A method of using a resorbable polymer base material in combination with an implant for the purpose of attenuating adhesions between the implant and surrounding tissue following a surgical procedure in a human patient, the method comprising:

providing a non-porous, resorbable polymer base material;

applying the resorbable polymer base material in a form of a resorbable thin membrane around the implant to thereby cover substantially all exposed surfaces of the implant, wherein the resorbable thin membrane comprises both a substantially uniform thickness except for an edge which is thicker and a resorbable polymer consisting essentially of:

a lactide polymer; or

a copolymer of two or more cyclic esters;

applying the implant and the resorbable thin membrane to a human patient in a region, which is susceptible to adhesions as a consequence of the surgical procedure; and

attenuating an occurrence of adhesions between the implant and surrounding tissue at the region within the human patient by way of the presence of the resorbable thin membrane positioned at the region within the patient.

2. (Previously Presented) The method according to claim 1, wherein:

the resorbable thin membrane comprises a substantially planar membrane of resorbable polymer base material having a first substantially smooth side and a second substantially smooth side, the substantially planar membrane of resorbable polymer base material having a substantially uniform composition;

the substantially planar membrane of resorbable polymer base material comprises a single layer of resorbable polymer base material;

the substantially uniform thickness is measured between the first substantially smooth side and the second substantially smooth side, and is between about 10 microns and about 100 microns;

the edge is 2 to 4 times thicker than the substantially uniform thickness; and

the single layer of resorbable polymer base material is adapted to maintain a smooth-surfaced barrier between the implant and surrounding tissue, and is adapted to be resorbed into a mammalian body within a period of less than approximately 24 months from an initial implantation of the implant into the patient.

3. (Previously Presented) The method according to claim 1, wherein:

the edge is 2-4 times thicker than the substantially uniform thickness;

the resorbable thin membrane comprises a layer of polymer base material; and

the polymer base material comprises about 60-80% of L-lactide and about 20-40% of D,L-lactide.

4. (Previously Presented) The method according to claim 1, wherein the edge is 2-4 times thicker than the substantially uniform thickness, and the resorbable thin membrane is in contact with the surfaces of the implant when it is applied to the implant.

5. (Previously Presented) The method according to claim 1, wherein:

the edge is 2-4 times thicker than the substantially uniform thickness; and

the step of applying the thin membrane onto the implant comprises a technique selected from the group consisting of wrapping, interweaving, blanketing, draping, taping, adjacent placement, juxtaposed positioning and sandwiching of the membrane onto the implant.

6. (Previously Presented) The method according to claim 1, wherein:

the edge is 2-4 times thicker than the substantially uniform thickness; and

the step of applying the thin membrane onto the implant comprises heat-shrinking the thin membrane around the implant.

7. (Previously Presented) The method according to claim 1, wherein the step of applying the thin membrane onto the implant comprises:

dissolving a polymer material in a solvent to form a solution; and

coating the implant with the solution.

8. (Previously Presented) The method according to claim 7, wherein:

the polymer material is selected from the group consisting essentially of a lactide polymer and a copolymer of two or more lactides; and

the solvent is selected from the group comprising ethyl acetate, acetonitrile, acetone, methyl ethyl ketone, tetrahydrofuran, methyl pyrole, and any combination thereof.

9. (Original) The method according to claim 8, wherein the solution comprises a concentration in the range of about 0.1 to about 5.0% of the polymer.

10. (Original) The method according to claim 7, further comprising a step of drying the coated implant before placement into a surgical site.

11. (Original) The method according to claim 10, wherein the step of drying comprises drying the coated implant in a vacuum oven.

12. (Original) The method according to claim 11, further comprising the step of air drying the coated implant before placement in the vacuum oven.

13. (Original) The method according to claim 7, wherein the step of coating the implant comprises spraying the implant with the solution.

14. (Previously Presented) The method according to claim 1, wherein the edge is 2-4 times thicker than the substantially uniform thickness, and the implant comprises biological material.

15. (Original) The method according to claim 14, wherein the biological material comprises grafting material.

16. (Original) The method according to claim 15, wherein the grafting material is selected from the group consisting of autograft material, xenograft material, allograft material, and combinations thereof.

17. (Original) The method according to claim 15, wherein the grafting material is selected from the group consisting of veins, arteries, heart valves, skin, dermis, epidermis, nerves, tendons, ligaments, bone, bone marrow, blood, white blood cells, red blood cells, gonadocytes, embryos, cells, adipose, fat, muscle, cartilage, fascia, membranes, pericardium, plura, periostium, peritoneum and dura.

18. (Original) The method according to claim 15, wherein the surrounding tissue is selected from the group comprising fascia, soft tissues, muscle, organs, fat, adipose, membranes, pericardium, plura, periostium, peritoneum, dura, bowels, intestines, ovaries, veins, arteries, epidermis, tendons, ligaments, nerves, bone and cartilage.

19. (Previously Presented) The method according to claim 1, wherein the edge is 2-4 times thicker than the substantially uniform thickness, and the implant comprises a transplanted organ.

20. (Original) The method according to claim 19, wherein the surrounding tissue is selected from the group comprising fascia, soft tissues, muscle, organs, fat, adipose, membranes, pericardium, plura, periostium, peritoneum, dura, bowels, intestines, ovaries, veins, arteries, epidermis, tendons, ligaments, nerves, bone and cartilage.

21. (Previously Presented) The method according to claim 1, wherein the edge is 2-4 times thicker than the substantially uniform thickness, and the implant comprises non-biological material.

22. (Original) The method according to claim 21, wherein the implant comprises a medical device.

23. (Original) The method according to claim 22, wherein the medical device is selected from the group consisting of bone graft substitutes, bone cement, tissue glues and adhesives, bone fixation members, defibrillators, eye spheres, sutures, staples, cochlear implants, pumps, artificial organs, non-resorbable membranes, bone growth stimulators, neurological stimulators, dental implants, guided tissue and guided bone regeneration membranes, eye lid weights and tympanostomy tubes.

24. (Original) The method according to claim 22, wherein the medical device comprises a fluid-filled prosthesis.

25. (Original) The method according to claim 23, wherein the surrounding tissue is selected from the group comprising fascia, soft tissues, muscle, organs, fat, adipose, membranes, pericardium, plura, periostium, peritoneum, dura, bowels, intestines, ovaries, veins, arteries, epidermis, tendons, ligaments, nerves, bone and cartilage.

26. (Original) The method according to claim 24, wherein the surrounding tissue is selected from the group comprising fascia, soft tissues, muscle, organs, fat, adipose, membranes, pericardium, plura, periostium, peritoneum, dura, bowels, intestines, ovaries, veins, arteries, epidermis, tendons, ligaments, nerves, bone and cartilage.

27. (Original) The method according to claim 24, wherein the fluid-filled prosthesis comprises a breast implant.

28. (Original) The method according to claim 27, wherein the breast implant comprises a saline implant contained within a silicone casing.

29. (Original) The method according to claim 22, wherein the implant comprises a pacemaker.

30-33. Cancelled.

34. (Previously Presented) The method according to claim 1, wherein the edge is 2-4 times thicker than the substantially uniform thickness, and the implant comprises grafting material selected from the group consisting of autograft material, xenograft material, allograft material, and combinations thereof.

35. (Original) The method according to claim 34, wherein the grafting material is selected from the group consisting of veins, arteries, heart valves, skin, dermis, epidermis, nerves, tendons, ligaments, bone, bone marrow, blood, white blood cells, red blood cells, gonadocytes, embryos, cells, adipose, fat, muscle, cartilage, fascia, membranes, pericardium, plura, periostium, peritoneum and dura.

36. (Previously Presented) The method according to claim 1, wherein the edge is 2-4 times thicker than the substantially uniform thickness, and the surrounding tissue is selected from the group comprising fascia, soft tissues, muscle, organs, fat, adipose, membranes, pericardium, plura, periostium, peritoneum, dura, bowels, intestines, ovaries, veins, arteries, epidermis, tendons, ligaments, nerves, bone and cartilage.

37-51. Cancelled.